



## Texas Commission on Environmental Quality

### Exemption §106.417 Checklist (Previously Standard Exemption 89) Ethylene Oxide (EtO) Sterilization Facilities

The following checklist has been developed so the Texas Commission on Environmental Quality (TCEQ) can confirm you meet exemption requirements. The questions are derived from §106.4, previously §116.211, and the exemption list. Please read all questions and check YES or NO (equivalent to True or False), or give specific information as applicable to your facility. If you do not meet all conditions of a specific exemption, you will not be allowed to operate the facility under exemption and you must apply for a construction permit as required under §116.111 prior to construction.

Part	YES	NO	Description
a)			<u>All</u> sterilizers must meet the following conditions:
1)			EtO will be handled by appropriately trained personnel
2)			Written records shall be maintained for a minimum of two years
A)			Records will include the date and time of each sterilizer operation cycle
B)			Records will include the total pounds of EO purchased and used per calendar year (listed as monthly totals)
C)			Records will include leak test results
3)			Leak tests of each sterilizer system will be performed at least every six months
			The EtO concentration will not exceed 10 ppm (measured at a distance of 1 centimeter from any portion of the sterilizer system)
			If a concentration greater than 10 ppm is detected, the sterilizer will be shutdown until the condition is corrected
4)			Sterilizer gas mixture will be 100% EtO
			Sterilizer gas mixture will be 12% EtO / 88% CFC-12
			Sterilizer gas mixture will be 10% EtO / 90% CO <sub>2</sub>
			Sterilizer gas mixture will be: _____
5A)			The sterilizer vent system exhaust stack will be uncapped and exhaust vertically upward
B)			The stack height shall be extended to at least 15 feet above the roof line of the building
			The stack tip shall be located at least 25 feet from any opening to the building interior, such as fresh air intake, unsealed windows, or pedestrian traffic areas
C)			Stack exit velocity will be at least 50 feet per second
b)			In addition to the conditions of (a), the following conditions apply <u>only to sterilizers that use less than 100 pounds of EtO per year</u> :
			Sterilizer will use less than 100 lb per year of EtO
1)			This sterilizer system vents entirely to atmosphere and will not use more than 0.5 pounds of EtO per cycle
			This sterilizer system uses nonrecirculating, water sealed vacuum systems and will not use more than 2 pounds of EtO charged per cycle
2)			Combination of sterilizers on the same or contiguous property will use less than 100 lb per year of EtO

Exemption §106.417, previously standard exemption 89, checklist

c) In addition to the conditions of (a) above, sterilizers that use between 100 and 1,000 lbs or EtO per year must answer the following:

- 1)     \_\_\_   \_\_\_     Sterilizer will use between 100 and 1,000 lb/yr of EtO  
      \_\_\_   \_\_\_     Construction at the facility has begun  
      \_\_\_   \_\_\_     Form PI-7 is complete and attached

Part	YES	NO	Description
2)	___	___	The sterilizer chamber exhaust shall vent through an emission control device that will continuously achieve an EtO removal efficiency of 99%
	___	___	Thermal incineration will not be used to control sterilizer exhaust emissions if chlorofluorocarbons are used as a diluent
	___	___	Within 60 days of start-up, the control device performance will be verified through stack testing
3)	___	___	There will be no discharge of water containing dissolved EtO through a sanitary sewer system
4)	___	___	Any combination of sterilizers located on the same or contiguous property under common ownership will be limited to a total EO usage of 1,000 pounds per year

NAME: \_\_\_\_\_

COMPANY NAME: \_\_\_\_\_ TITLE: \_\_\_\_\_

FACILITY NAME: \_\_\_\_\_

PHONE #: ( ) \_\_\_\_\_ ACCOUNT ID #: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

FAX #: ( ) \_\_\_\_\_

LOCATION: \_\_\_\_\_

\_\_\_\_\_  
SIGNATURE OF COMPANY OFFICER

\_\_\_\_\_  
DATE